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Government Of India
Patent Office
Todi Estates, 3rd Floor,
Lower Parel (West)
Mumbai - 400 013

THE PATENTS ACT, 1970

IT IS HEREBY CERTIFIED THAT, the annex is a true copy of Application and Provisional Specification filed on 12/04/2004 in respect of Patent Application No.437/MUM/2004 of DR. THAKKAR NAVIN NARSINHBHAI, 2/A, AGAM NIGAM NAVNIRMAN CO.OP.SOCIETY, ANANDWADI, ISANPUR, AHMEDABAD - 382443, GUJARAT STATE, INDIA, AN INDIAN NATIONAL.

This certificate is issued under the powers vested in me under

Section 147(1) of the Patents Act, 1970.

..... Dated this 16th day of May 2005.

(A. T. PATRE)
ASST. CONTROLLER OF PATENTS & DESIGNS.

FORM-1

THE PATENTS ACT, 1970
(39 of 1970)
APPLICATION FOR GRANT OF A PATENT
[See sections 5(2), 7, 54 and 135 ; rule 39]

1. I,
(a) Dr. THAKKAR NAVIN NARSINHBHAI
(b) 2/A, Agam Nigam Navnirman Co. Op. Society,
Anandwadi, Isanpur, Ahmedabad-382443,
Gujarat State, India
(c) An Indian National,
2. hereby declare-
- (a) that I am in possession of an invention titled "AN IMPLANT ASSEMBLY FOR PROXIMAL FEMORAL FRACTURE"
(b) that the Provisional specification relating to this invention is filed with this application.
(c) That there is no lawful ground of objection to the grant of a patent to me.
3. further declare that the inventor for the said invention is
(a) Dr. THAKKAR NAVIN NARSINHBHAI
(b) 2/A, Agam Nigam Navnirman Co. Op. Society,
Anandwadi, Isanpur, Ahmedabad-382443,
Gujarat State, India
(c) An Indian National.

4. That my address for service in India is as follows:

Y.J. TRIVEDI and JATIN Y. TRIVEDI
Patent & Trade Mark Attorney & Advocate.
"YAGNAJYOT" Bungalow,
Opp. Kashiram Agrawal Hall,
B/h. Jahanvee Restaurant, Polytechnic,
Ahmedabad-380 015, Gujarat State, India

5. That to the best of my knowledge, information and belief the fact and matters stated herein are correct and that there is no lawful ground of objection to the grant of patent to me on this application.

6. Following are the attachment with the application:

- (a) Provisional specification (3 copies).
(b) Priority document (s).
(c) Form of authorization - Form -26.
(d) Fee Rs. in cheque bearing No. date on Bank.

I request that a patent may be granted to me for the said invention.

Dated this 6th Day of April, 2004.

N. N. Thakkar

(Dr. THAKKAR NAVIN NARSINHBHAI)

To
The Controller of Patents
The Patent Office,
Mumbai.

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DUPLICATE

FORM - 2

THE PATENTS ACT, 1970
(39 of 1970)

PROVISIONAL SPECIFICATION
(SECTION 10; rule 13)

DUPLICATE

"AN IMPLANT ASSEMBLY FOR PROXIMAL FEMORAL FRACTURE"

Dr. THAKKAR NAVIN NARSINHBHAI

An Indian National having his address at
2/A, Agam Nigam Navnirman Co. Op. Society,
Anandwadi, Isanpur, Ahmedabad-382443,
Gujarat State, India.

The following specification particularly describes the
nature of this invention:-

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This invention relates to AN IMPLANT ASSEMBLY FOR PROXIMAL FEMORAL FRACTURE. This invention particularly relates to AN IMPLANT ASSEMBLY FOR PROXIMAL FEMORAL FRACTURE which provides controlled collapse without sacrificing stability of the implant.

Incidence of unstable proximal fractures in elderly is very high world wide and management of these geriatric patients has become challenge. Unstable proximal femur fractures are different entity in the young (high-energy traffic accidents) and the elderly patients (low energy falls). In young patients anatomic reconstruction and stable osteosynthesis can be preserved during after treatment by means of non-wt bearing. In geriatric patients with unstable proximal femur fractures, senile osteoporosis and the need for early mobilization with assisted full weight bearing, requires higher demands on the biomechanical properties of the implant assembly. Such as

- The implant should acquire minimum area of the bone to provide Anatomical reconstruction with stable biological (MINIMALLY INVASIVE) osteosynthesis.
- At the same time implant should be capable to react effectively to large, dynamic (in magnitude and direction) and cyclic physiological loads (assisted weight bearing) during rehabilitation of elderly patients by giving desired controlled collapse.

Normally there are two categories in which implant assembly for proximal femoral fracture are divided:

1. **EXTRAMEDULLARY IMPLANT SYSTEMS or SIDE PLATE DEVICES** : - in this category, the devices are as follows:

1) SP NAIL AND PLATE: It mainly comprises of 3 parts named SP Nail which is triflanged in its whole length and cannulated without mores taper for holding proximal fragment, I T Plate and Screws used for holding distal fragment and Junction :

This device holds proximal fragment well providing rotational stability due to triflanged design. But at the same time it has many disadvantages making the device obsolete:

- A. It has a weak junction can not with stand strong varus lever arm forces so loss of reduction and neck shaft angle as junction fails first .
- B. It does not allow collapse at fractured site.
- C. Technique adopted for insertion was purely hammering without pre drilling, producing large hole at lat cortex, shattering of bone and distraction at fracture site. Whole length of nail triflanged, so that also keep fracture distracted till junction fails.
- D. It can not prevent excessive medial displacement of shaft when there is comminution in lateral wall of greater trochanter

2) J – NAIL :- It is an improvement over Sp Nail Plate in which everything is same except junction is made fixed to make it strong to withstand various longer lever arm forces.

Disadvantage:

- A. As the junction is made fixed implant does not allow collapse. Fracture gap is there in comminuted unstable fracture moreover traction on table and hammering of J Nail without pre-drilling increases gap. This gap is not allowed to collapse post operatively due to fixed junction, leading to delayed union and later on implant failure .this causes the nail to either go in to hip joint or it breaks at junction of nail and plate.
- B. It does not provide prevention against excessive medial displacement of shaft.

3). ANGLE BLADE PLATE: - In this type of devices Biomechanics is same as J nail except blade part holding proximal fragment has u profile instead of triflanged nail to provide higher stability to the implant.

But It has same disadvantages as J nail with added disadvantage of technically demanding skill of surgeon to insert it inside the bone.

4). DYNAMIC HIP SCREW: - This type of implants comprises of three parts named part holding proximal fragment with single round large diameter screw of 12 mm, part holding distal fragment having side plate with screws and a junction which can be of two types either a barrel and plate junction which is a fixed, strong and angled junction or a Sliding screw and barrel junction which allows collapse well.

Disadvantages:

- A. Single round screw and round outer surface of barrel (within a round bony tunnel) can not give rotation stability to bone of proximal fragment. This rotation instability of proximal fragment can lead to implant failure.
- B. There is no means of support provided lateral wall of greater trochanter above site of entry of D.H.S., so medial displacement of distal shaft can not be prevented by D.H.S., when there is comminution in lateral wall of greater trochanter.

2. INTRAMEDULLARY DEVICES :-

1). ENDERS NAILING : Here multiple elastic flexible Enders' nails are passed from medial supracondylar region to head & neck of femur.

Disadvantages:

- A. Hold in proximal fragments is variable so it backs out producing pain on medial side of knee requiring second operation.
- B. Hold in distal fragments is poor so does not give rotational stability, external rotation deformity of limb is commonly found.

2) GAMMA NAIL :

DISADVANTAGES :

- A. It is having single round large screw passing through nail to hold proximal fragment does not give enough rotational stability to proximal fragment in unstable fractures and thus fails.
- B. Larger hole in the nail weakens nail and gives rise to higher chances of breakage of implant.
- 3. Larger proximal diameter of nail removes more bone and may cause shattering or comminution
- 4. Large diameter of nail in funnel shape of canal raises stress at the tip of nail and later on incidence of # beneath nail tip of shaft femur is more noticed
- 5. Jumbo jig obstructs imaging in lateral view (axial view) pre operatively and thus technically becomes difficult
- 6. Does not provide any inbuilt ante version in proximal hole or jig , so to accommodate ante version of femur , requires rotation of jig or limb externally., so distal locking becomes difficult or cumbersome - poster lateral to anteromedial.
- 7. Many a times it collapses excessively or it does not collapse at all due to abutting of screw . So it lacks controlled desired collapse - reaction to physiological loads during weight bearing at post operative rehabilitation..
- 8. Distal end is not having anterior congruent curvature , so it causes pointing effect- post of thigh pain.

Objects of the invention:

So with the goal of providing an implant assembly which provides good rotational stability to Proximal Fragment while collapse is occurring inventor has invented this new device.

The further object of this invention is to provide an implant assembly with a shape that can resist rotation.

The further object of this invention is to provide an implant assembly which has good hold over the distal fragment without opposing controlled collapse of the implant during varus forces.

The further object of this invention is to provide an implant assembly which acquires minimum area of the bone allowing Anatomical reconstruction with stable biological (MINIMALLY INVASIVE) osteosynthesis.

The further object of this invention is to provide an implant assembly which has anatomic profile same as of the human bone to eliminate pointing effect which is responsible for thigh pain.

The further object of this invention is to provide an implant assembly which is cost effective and so a normal man can also afford it.

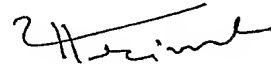
Description of the system: -

The invention is described as under:

The unit comprises of proximal rod which has a reducing diameter in three steps to match the shape with shape of the human femoral bone, proximal sliding hip pins with distance between them nearly equal to their diameter. Proximal sliding hip pins are placed such that they make an angle of 10 degree to the proximal rod which makes the implant suitable to anatomic profile of the femoral bone. Distal interlocking screw inserted into proximal rod at 90 degree. Proximal sliding hip pins are of non uniform cross section having pointed shape with smaller diameter cross section in the lower half of the hip pin while upper half is made up of round

cross section with larger diameter. Distal dynamic hole and static hole are given in the lower part of the proximal rod to accommodate the distal interlocking screw. Dynamic hole is made of larger diameter than that of the distal interlocking screw to allow collapse in vertical direction during post operating period.

Dated this 7th day of April 2004.



(Y.J. TRIVEDI)

Authorised Agent of the Applicant

To,
The Controller of Patents,
The Patent Office, Mumbai.